NVAC Vaccine Safety Working Group Update

NVAC Meeting
September 16, 2008

Andrew Pavia, MD
George & Esther Gross Presidential Professor
Department of Pediatrics
University of Utah School of Medicine

Working Group Charge

1. Undertake and coordinate a scientific review of the draft ISO research agenda. Advise on:
   a. Content of ISO draft research agenda (e.g., are the topics on the agenda appropriate? Should other topics be included?)
   b. Prioritization of research topics
   c. Possible scientific barriers to implementing the research agenda and suggestions for addressing them
2. Review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.

Working Group Members

Name	Discipline	Group Representation
Andy Pavia	Pediatric and Adult Infectious Diseases, NVAC Member	Academia
Bennett Shaywitz	Neurology	Academia
Chris Carlson	Genomics	Academia
Corry Dekker	Pediatrics, NVAC Member	Academia
Elizabeth Miller	Vaccine Safety in the UK	Professional Organization
Gerald Medoff	Immunology	Professional Organization
Gus Birkhead	Epidemiology, NVAC Member	State Health Department
Jim Mason	Public Health, NVAC Member	CDC Director/ASH
Lance Gordon	Immunology, NVAC Member	Industry

Working Group Members, cont.

Name	Discipline Used for Initial Selection	Group Representation
Lawrence Gostin	Ethics/Law	Academia
Lynn Goldman	Toxicology/Environmental Health	Academia
Marie McCormick	Maternal and Child Health, NVAC member	Academia
Mark Feinberg	Immunology, NVAC Member	Industry
Paul-Henri Lambert	Global aspects of vaccine safety	Professional Organization
Sean Hennessy	Pharmacoepidemiology	Academia
Steve Goodman	Biostatistics	Academia
Tawny Buck	Parent of a child injured by a vaccine	Consumer Groups
Trish Parnell	Parent of a child with an infectious disease, NVAC member	Consumer Groups

Working Group Ex-Officios

- Dan Salmon, NVPO/HHS
- Larry Pickering, NCIRD/CDC and ACIP
- John Iskander, ISO/CDC
- Karen Midthun, CBER/FDA
- Robert Ball, CBER/FDA
- Geoff Evans, VICP/HRSA
- Barbara Mulach, NIAID/NIH
- Jessica Bernstein, NIAID/NIH
- Florence Houn, FDA
- Carmen Collazo, FDA
- Alice Kau, NIH
- Peter Scheidt, NICHD
- Renata Engler, DoD

Summary of ISO Scientific Agenda Draft Recommendations

1. Respond to emerging issues and conduct core, required scientific activities
2. Enhance vaccine safety public health and clinical guidance capacity in 7 areas
3. Address 5-Year research needs

ISO Agenda Draft Recommendations
#3 5-Year Research Needs (30 items)

Item	5-Year Research Needs (30 items)
A	**Specific Vaccine Safety Questions (7 items)**
B	**Thematic Area: Vaccines and Vaccination Practices (8 items)**
C	**Thematic Area: Special Populations (7 items)**
D	**Thematic Area: Clinical Outcomes (8 items)**

ISO Agenda Draft Recommendations
#2: Enhance Vaccine Safety Public Health and Clinical Guidance Capacity in 7 Areas

Item	Capacity Area
A	**Infrastructure for Vaccine Safety Surveillance: Vaccine Adverse Event Reporting System (VAERS)**
B	**Infrastructure for Vaccine Safety Surveillance and Research: Vaccine Safety Datalink (VSD) Project**
C	**Epidemiologic and Statistical Methods for Vaccine Safety**
D	**Laboratory Methods for Vaccine Safety**
E	**Genomics and Vaccine Safety**
F	**Case Definitions, Data Collection, and Data Presentation for Adverse Events Following Immunization**
G	**Vaccine Safety Clinical Practice Guidance**

Progress since last update

- Vaccine Safety Working Group divided into 4 subgroups, each focusing on one research topic and 2 capacity topics
- Frequent conference calls within subgroups and as a larger Working Group
- Briefings with ISO
  - Q & A
  - Supplemental background information
  - CISA

Progress since last update

- Vaccine Safety Working Group divided into 4 subgroups, each focusing on one research topic and 2 capacity topics

Group	Group Members	Research Topic	Capacity Topic(s)
1	1. Corry Dekker 2. Bennett Shaywitz 3. Sean Hennessy 4. Trish Parnell	1. Specific Vaccine Questions	1. VAERS Infrastructure 2. VSD Infrastructure
2	1. Gus Birkhead 2. Steven Goodman 3. Elizabeth Miller 4. Jim Mason	1. Clinical Outcomes	1. Epi/Statistical Methods 2. Case Definitions
3	1. Chris Carlson 2. Marie McCormick 3. Paul-Henri Lambert 4. Tawny Buck	1. Special Populations	1. Lab Methods 2. Genomics
4	1. Mark Feinberg 2. Lynn Goldman 3. Gerald Medoff 4. Lance Gordon	1. Vaccines and Vaccinations	1. Clinical Guidance 2. CISA

Emerging Themes

- Resources, funding, and capacity of ISO
  - Decision to use a zero-based budgeting model to evaluate research needs
- Involvement of other federal partners
- Need for research in risk perception and communication
- Recurrent tensions between scientific merit and public concern over vaccine safety issues
  - If not research, what are the optimal ways to address?
- The challenge of evaluating broad research categories and the need for an overarching framework

Discussion Highlights

- What is the significance of singling out a particular product or vaccine component on the agenda?
- What is the value of further study of thimerosal and tics/Tourette's/speech and language delays considering limited exposure through vaccines in the United States?

Discussion Highlights (2)

- What outcomes should ISO consider for genomic studies? What other considerations does ISO need to take into account to do genomic studies?
- Do severe adverse events share risk factors with more common acute reactions, and if so, what would be the best way to study?

Discussion Highlights (3)

- Value of a retrospective study of policy-making, risk management, and risk perception during vaccine safety controversies, including the use of scientific data in decision-making

Public Engagement

- Planning Steering committee is being formed, which includes NVAC Vaccine Safety Working Group subgroup on Public Engagement (Jim Mason, Tawny Buck, Trish Parnell)
- Working Group members are invited to participate in public engagement activities, planned to occur in November
- Reports on the public engagement activities will inform the Working Group's recommendations

Timeline

- Continue to review and prioritize the content of the ISO Scientific Agenda in subgroups
- Review recommendations by other subgroups (mid-October 2008)
- Participate in Public Engagement activities and incorporate (November 2008)
- Draft recommendations and priorities (December 2008/January 2009)
- Present recommendations to NVAC (February 2009)